REMARKS

Applicant acknowledges the current status of the claims, as reported in Office Action dated 22 May 2006. Claims 1-20 are pending; and claims 1-20 are subject to restriction and/or election requirement. The Examiner has required restriction to one of the seventy (70) groups under 35 U.S.C. §121 as listed on pages 2-7 of the instant Office Action.

Specifically, the Examiner has restricted the claims of the present application as follows:

I. Claims 1-7, drawn to a method of detecting a deantigenized T cell epitope having a binding affinity to a soluble MHC class I molecule and a method for generating a modified polypeptide; classified in Class 435, subclass 7.1.

II. Claims 1-7, drawn to a method of detecting a deantigenized T cell epitope having a binding affinity to a soluble MHC class II molecule and a method for generating a modified polypeptide; classified in Class 435, subclass 7.1.

III-VIII. Claims 8 and 12-16, drawn to a deantigenized MHC class I T cell epitope and a modified polypeptide comprising the said epitope; classified in Class 530, subclass 328 and Class 424, subclass 185.

IX-XIV. Claims 8 and 12-16, drawn to a deantigenized MHC class II T cell epitope and a modified polypeptide comprising the said epitope; classified in Class 530, subclass 328 and Class 424, subclass 185.

XV-XX. Claims 9-11 and 18-20, drawn to a polynucleotide encoding a deantigenized MHC class I T cell epitope and a polynucleotide encoding a modified polypeptide that comprises the said epitope, expression vector and host cell thereof; classified in Class 536, subclass 23.5 and Class 435, subclasses 320.1 and 252.3.

XXI-XXVI. Claims 9-11 and 18-20, drawn to a polynucleotide encoding a deantigenized MHC class II T cell epitope and a polynucleotide encoding a modified polypeptide that comprises the said epitope, expression vector and host cell thereof; classified in Class 536, subclass 23.5 and Class 435, subclasses 320.1 and 252.3.

XXVII-XLII. Claim 17, drawn to a method of preventing or treating a disease or disorder in a vertebrate, comprising using a modified polypeptide comprising a deantigenized MHC class I T cell epitope; classified in Class 424, subclasses 130.1.

XLIII-XLVIII. Claim 17, drawn to a method of preventing or treating a disease or disorder in a vertebrate, comprising using a modified polypeptide comprising a deantigenized MHC class II T cell epitope; classified in Class 424, subclass 130.1.

XLIX-LXIV. Claim 17, drawn to a method of diagnosing a disease or disorder in a vertebrate, comprising using a modified polypeptide comprising a deantigenized MHC class I T cell epitope; classified in Class 435, subclass 7.1.

LXVI-LXX. Claim 17, drawn to a method of diagnosing a disease or disorder in a vertebrate, comprising using a modified polypeptide comprising a deantigenized MHC class II T cell epitope; classified in Class 435, subclass 7.1.

The Examiner further requires election of species. The asserted species consist of a single disclosed species of dissociation constant for the binding of the deantigenized T cell epitope to MHC (for example, greater than or equal to about $5x10^{-5}$ M).

Applicant respectfully traverses the restriction of claims and requests reconsideration and withdrawal of restriction requirement.

Proper restriction between independent and distinct inventions claimed in the same application requires that (1) the invention must be independent and distinct as claimed and (2) there must be a serious burden placed on the Examiner by not requiring election. If either criteria is not met, restriction is not proper. The term "independent" means that there is no disclosed relationship between the two or more subjects disclosed in a patent application. The term "distinct", means two or more subjects as disclosed are related but are capable of separate manufacture, use or sale as claimed, and are patentable over each other. (see M.P.E.P. §802.01). Further, with respect to the burden of the examination, M.P.E.P. §803 states in relevant part, "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions."

Applicant asserts that the claims are drawn to a single inventive concept and a single inventive effort, the search and examination of which would not place a serious burden on the Examiner. The claims are different aspects and embodiments of the same disclosed subject matter.

Applicant's invention is directed to a method for detecting a deantigenized T cell epitope wherein the deantigenized T cell epitope has a binding affinity to a soluble MHC molecule less than the binding affinity of the T cell epitope to the same MHC molecule. Additional embodiments of the invention include the product, the deantigenized T cell epitope, identified by the method, methods of using the deantigenized T cell epitope to diagnose, prevent or treat a disease. Thus, the method for detecting a deantigenized T cell epitope, the deantigenized T cell epitope identified by the method and method of using the deantigenized T cell epitope to diagnose, prevent or treat a disease of the invention, are all linked. Therefore, the subject matter of Applicant's Patent application are not "independent" as determined by M.P.E.P. 802.01.

The deantigenized T cell epitopes of the invention are produced by the methods disclosed in the application. Thus, the method of detecting a deantigenized T cell epitope, the deantigenized T cell epitope identified by the method, and use of the deantigenized T cell epitope identified by the method represent different embodiments of one invention. Therefore, the subjects disclosed in the instant application do not meet the criteria for "distinct" as defined in M.P.E.P. § 802.01.

Furthermore, according to § 806.05 of the M.P.E.P., a "separate field of search" means, "it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists" (*emphasis added*).

The inventions of Group I and II are classified in Class 435, subclass 7.1; Group III-VIII and IX-XIV are classified in Class 530, subclass 328 and Class 424, subclass 185; Groups XV-XX and XXI-XXVI are classified in Class 536, subclass 23.5 and Class 435, subclasses 320.1 and 252.3; Group s XXVII-XLII andXLIII-XLVIII are classified in Class 424, subclass 130.1; and Groups XLIX-LXIV and LXVI-LXX are classified in Class 435, subclass 7.1. As such, the searches with regard to inventions in the same class and subclass would be co-extensive and would not involve a serious burden on the Examiner.

Specifically, the Examiner has restricted the method of claims 1-7 into two groups based on the class of MHC molecule the T cell epitope binds. Applicant respectfully submits that results of search of deantigenized T cell epitopes capable of binding soluble MHC molecules would encompass all MHC molecules irrespective of the class of MHC molecule. Applicant respectfully requests reconsideration of the requirement for restriction of claims 1-7 into two groups in the present application because the examination of claims 1-7 together in the application would not place a serious burden on the Examiner, since the prior art search for Groups I and II would be co-extensive (i.e., the field of search for these inventions will invariably contain much of the same relevant art).

On page 9 items 8 and 9, the Examiner asserts that inventions listed at Groups I and II and Groups III-VIII, related as process of making and product made are distinct because a known T cell epitope may be subjected to an Alanine scan of each position in the peptide, and the altered epitope possessing low to absent binding may be substituted into the native protein sequence in place of the T cell epitope. Applicant respectfully submits that Applicant's invention is directed to a method of detecting a deantigenized T cell epitope. In other words, merely generating T cell epitopes with modified amino acid sequences, including subjecting the epitope to Alanine scan of each position, does not produce a deantigenized T cell epitope. A method by which one can detect which of the altered T cell epitopes is the appropriate deantigenized T cell epitope is required, and this is the subject matter of the invention. Therefore, the product of groups III-VIII can only be generated by practicing the method

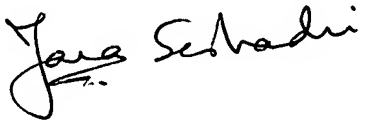
of Group I. Applicant respectfully requests reconsideration of the requirement of restriction of claims 1-7, and claims 8 and 12-16 into Group I and II, and Groups III-VIII respectively.

The present application contains a single searchable, unifying aspect, i.e. method of detecting a deantigenized T cell epitope with binding affinity to soluble MHC molecule less than the binding affinity of the T cell epitope; and the deantigenized T cell epitope identified using the aforementioned method. Therefore, Applicant submits that the Examiner can search and examine the application without serious burden. Thus, Applicant respectfully submits that Applicant's invention does not meet the threshold of "two or more independent and distinct" inventions as required in 35 U.S.C. §121 and as such the restriction requirement is improper. In view of the foregoing, Applicant respectfully requests withdrawal of the restriction requirement.

Notwithstanding Applicant's belief that the restriction and requirement of election are improper, and without in any way acquiescing to the reasons for the requirements set forth in the Office Action, but in order to be fully responsive to the Office Action, Applicant provisionally elects for examination the claims of Group I.

As to election of a species, Applicant elects the disclosed species of dissociation constant $5x10^{-3}$ M for the binding of the deantigenized T cell epitope to soluble MHC molecule. It is Applicant's understanding that the species election is for searching purposes only and, upon a finding of allowability of the elected species, the remaining species also will be searched. Applicant also reserves the right to traverse the restriction between the non-elected groups and species in this or a separate application.

Respectfully submitted,



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